Remarks

Claims 1-75 are pending in this application. Claims 40 and 61 have now been amended. Applicants respectfully assert that all amendments are supported by the original disclosure and do not introduce new matter. Moreover, Applicants further respectfully assert that the amendments merely clarify the scope of the claims.

Election/Restrictions

The Examiner has now requested a restriction to one of the following inventions under 35 U.S.C. 121:

I. Claims 1 -23 and 31-38, drawn to a transgenic non-human mammal, wherein the mammal carries a targeted disruption in the coding sequence of an endogenous surfactant protein C (SP-C) gene and wherein the targeted disruption inhibits production of wild- type surfactant protein C so that the phenotype of the mammal is characterized by a pulmonary disorder condition consistent with changes in humans with familial SP-C deficiency, classified in class 800, subclass 8.

II. Claims 24-30, drawn to a method of testing an agent for effectiveness against a pulmonary condition using a transgenic mouse that is homozygous for an surfactant protein C null allele, classified in class 800, subclass 3.

III. Claims 40-41, drawn to a method of treating pulmonary disease in a subject comprising the administration to a subject in need of such treatment a therapeutically effective amount of a formulation comprising a SP-C therapeutic wherein said therapeutic is an antibody, classified in class 530, subclass 388.2.

IV. Claims 40 and 42, drawn to a method of treating pulmonary disease in a subject comprising the administration to a subject in need of such treatment a therapeutically effective amount of a formulation comprising a SP-C therapeutic wherein said therapeutic is a protein, classified in class 514, subclass 2.

V. Claims 40 and 43-46, 48-50, 52, and 54-62, drawn to a method of treating pulmonary disease in a subject comprising the administration to a subject in need of such treatment a therapeutically effective amount of a formulation comprising a SP-C therapeutic wherein said therapeutic is a nucleic acid and is delivered via retrovirus, classified in class 514, subclass 44.

VI. Claims 40 and 43-45, 47-51, and 54-62, drawn to a method of treating pulmonary disease in a subject comprising the administration to a subject in need of such treatment a therapeutically effective amount of a formulation comprising a SP-C therapeutic wherein said therapeutic is a nucleic acid and is delivered via a liposome, classified in class 514, subclass 44.

VII. Claims 40 and 43-45, 47-50, 52-62, drawn to a method of treating pulmonary disease in a subject comprising the administration to a subject in need of such treatment a therapeutically effective amount of a formulation comprising a SP-C therapeutic wherein said therapeutic is a nucleic acid and is delivered via adenovirus, classified in class 514, subciasr 44.

VIII. Claim 63, drawn to a method for prescribing treatment for airway hyperresponsiveness and/or airflow limitation associated with a respiratory disease involving an inflammatory response in a mammal, comprising administering to the lungs of a mammal a SP-C therapeutic agent, wherein said agent is an antibody, classified in class 530, subclass 388.2.

IX. Claim 63, drawn to a method for prescribing treatment for airway hyperresponsiveness and/or airflow limitation associated with a

respiratory disease involving an inflammatory response in a mammal, comprising administering to the lungs of a mammal a SP-C therapeutic agent, wherein said agent is a protein, classified in class 514, subclass 2.

X. Claim 63, drawn to a method for prescribing treatment for airway hyperresponsiveness and/or airflow limitation associated with a respiratory disease involving an inflammatory response in a mammal, comprising administering to the lungs of a mammal a SP-C therapeutic agent, wherein said agent is a nucleic acid, classified in class 514, subclass 44.

XI. Claims 64-66, 72, and74-75, drawn to a formulation for protecting a mammal from airway hyperresponsiveness, airflow limitation and/or airway fibrosis associated with a respiratory disease involving inflammation, comprising an anti-inflammatory agent effective for reducing eosinophilic inflammation and a SP-C therapeutic agent, wherein said agent is an antibody, classified in class 530, subclass 388.2.

XII. Claims 64-67 and 74-75, drawn to a formulation for protecting a mammal from airway hyperresponsiveness, airflow limitation and/or airway fibrosis associated with a respiratory disease involving inflammation, comprising an anti-inflammatory agent effective for reducing eosinophilic inflammation and a SP-C therapeutic agent, wherein said agent is a protein, classified in class 514, subclass 2.

XIII. Claims 64-66, 68-69 and 74-75, drawn to a formulation for protecting a mammal from airway hyperresponsiveness, airflow limitation and/or airway fibrosis associated with a respiratory disease involving inflammation, comprising an anti-inflammatory agent effective for reducing eosinophilic inflammation and a SP-C therapeutic agent, wherein said agent is a nucleic acid and is delivered with a liposome, classified in class 514, subclass 44.

XIV. Claims 64-66, 68, 70-71 and 74-75, drawn to a formulation for protecting a

mammal from airway hyperresponsiveness, airflow limitation and/or airway fibrosis associated with a respiratory disease involving inflammation, comprising an anti- inflammatory agent effective for reducing eosinophilic inflammation and a SP-C therapeutic agent, wherein said agent is a nucleic acid and is delivered with a adenovirus. classified in class 514, subclass 44.

XV. Claims 64 and 73-75, drawn to a formulation for protecting a mammal from airway hyperresponsiveness, airflow limitation and/or airway fibrosis associated with a respiratory disease involving inflammation, comprising an anti-inflammatory agent effective for reducing eosinophilic inflammation and a SP-C therapeutic agent, wherein said agent is a nucleic acid and a protein, classified in class 514, subclass 44.

Applicants hereby respectfully traverse the restriction. Applicants point out that this restriction requirement is improper for ***numerous*** reasons, as follows:

The Examiner contends that Groups III-VII are distinct from each other in that each of groups III-VIII is drawn to a method of treating pulmonary disease in a subject, however each method would require separate and different protocols to facilitate the method of treating a pulmonary disease. The delivery of an antibody, protein, and nucleic acid via retrovirus, adenovirus, or liposome are each distinct methods of treatment and thus would require materially distinct protocols to practice the claimed methods

All of the claims in Groups III-VII involve the same basic method. That is, the present claims are all directed to a method of treating pulmonary disease in a subject. Groups III through VII are merely the makeup of the Markush group in dependent claim 40, which depends from independent claim 39. Claim 39 does not appear to fall within *any* of the groups of inventions put together by the Examiner.

The MPEP §803.02 states that "if the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner ***must*** examine all the members of the Markush group in the

claim on the merits, even though they are directed to independent and distinct inventions (emphasis added). In such a case, the examiner is not to require a restriction.

Even then, this subsection deals with Markush-type generic claims, which include a plurality of alternatively usable substances or members. In most cases, a recitation by enumeration is used because there is no appropriate or true generic language. While a Markush-type claim can include independent and distinct inventions, this is true only where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). In applications containing claims of that nature, the examiner may require a provisional election of a single species prior to examination on the merits. The provisional election will be given effect in the event that the Markush-type claim should be found not allowable. Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable over the prior art, examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration. Should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended.

Additionally, the art is a very well defined, relatively small field. MPEP §803 states that even if an application includes several independent or distinct inventions, they should all be considered together in a single prosecution if that can be done without placing a serious burden on the Examiner. Even if it is assumed that the claims of the present invention cover more than one distinct invention, they should all be considered together since largely the same art would have to be searched for each claim. The present invention comes down to simply methods and compositions for the treatment of pulmonary disease.

The Examiner himself has indicated that all of the Groups fall into one of just ***two*** search classes (514 and 530 and the Examiner has not shown that the Examination of any one of the groups would not require the same or substantially the same search of the art. Therefore, the

Examiner has indicated that there is a limited area of search required and therefore considering all claims together would not place a serious burden on the Examiner.

The Examiner is urged to reconsider the restriction/election requirement as breaking down what is really a single invention into such an inordinate number of restricted groups would place an *enormous* financial burden on our client, a nonprofit Children's Hospital, to file such additional divisional applications. Just the payment of U.S.P.T.O. fees alone for such filings would total over ***$150,000.00*** without taking into account the legal fees associated time and expense of preparing, filing and prosecuting these applications.

For these reasons, the restriction requirement defined by the Examiner is improper. Accordingly, it is respectfully requested that the restriction requirement be withdrawn. While Applicants believe that this would not in any way place an undue burden on the Examiner, Applicants strongly believe that the Examiner should at the very least consolidate Groups III through VII into a single group. Failing that, the Examiner should consolidate those claims that fall within the same search classes.

If the event the Examiner is willing to consolidate the claim groups, Applicants respectfully request that the Examiner reconsider the extent of the Restriction Requirement and rejoin Groups III through VII. If the Examiner would agree to such rejoinder, Applicants elect the rejoined Groups III-VII for prosecution on the merits. Alternatively, Applicants request that the Examiner reconsider the extent of the Restriction Requirement and rejoin Groups III through VII and make the restriction an election of species that can be rejoined upon the allowance of a linking claim.

In the event that the restriction requirement is maintained, Applicants hereby elect Group IV.

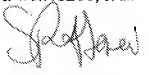
Applicants' undersigned attorney has made a good faith effort to be responsive to the restriction requirement made in the Office Action dated March 28, 2006. If the Examiner would like to discuss the restriction requirement or to have Applicants provide any clarification of its

terms, he is invited to contact Applicants' undersigned attorney at the phone number given below.

The Commissioner for Patents is hereby authorized to charge any deficiency or credit any overpayment of fees to Frost Brown Todd LLC Deposit Account No. 06-2226.

Respectfully submitted,

JEFFREY A. WHITSETT, et al.



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